

FIG. 1

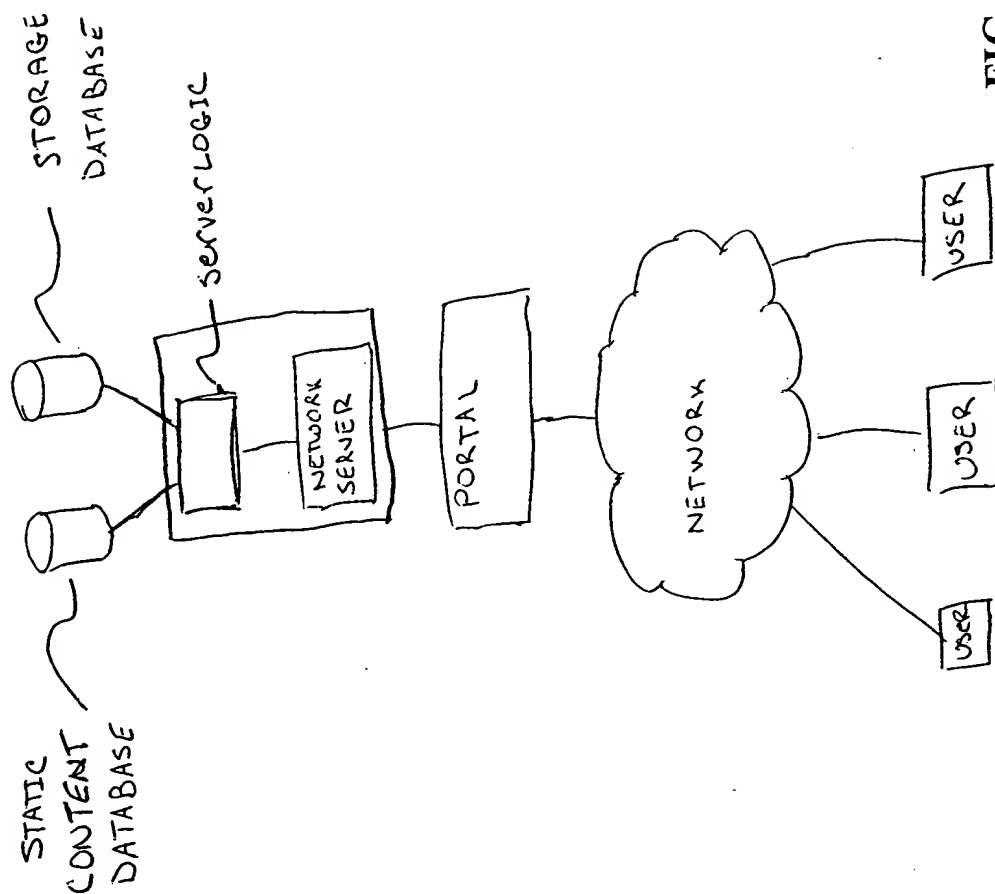


FIG. 2

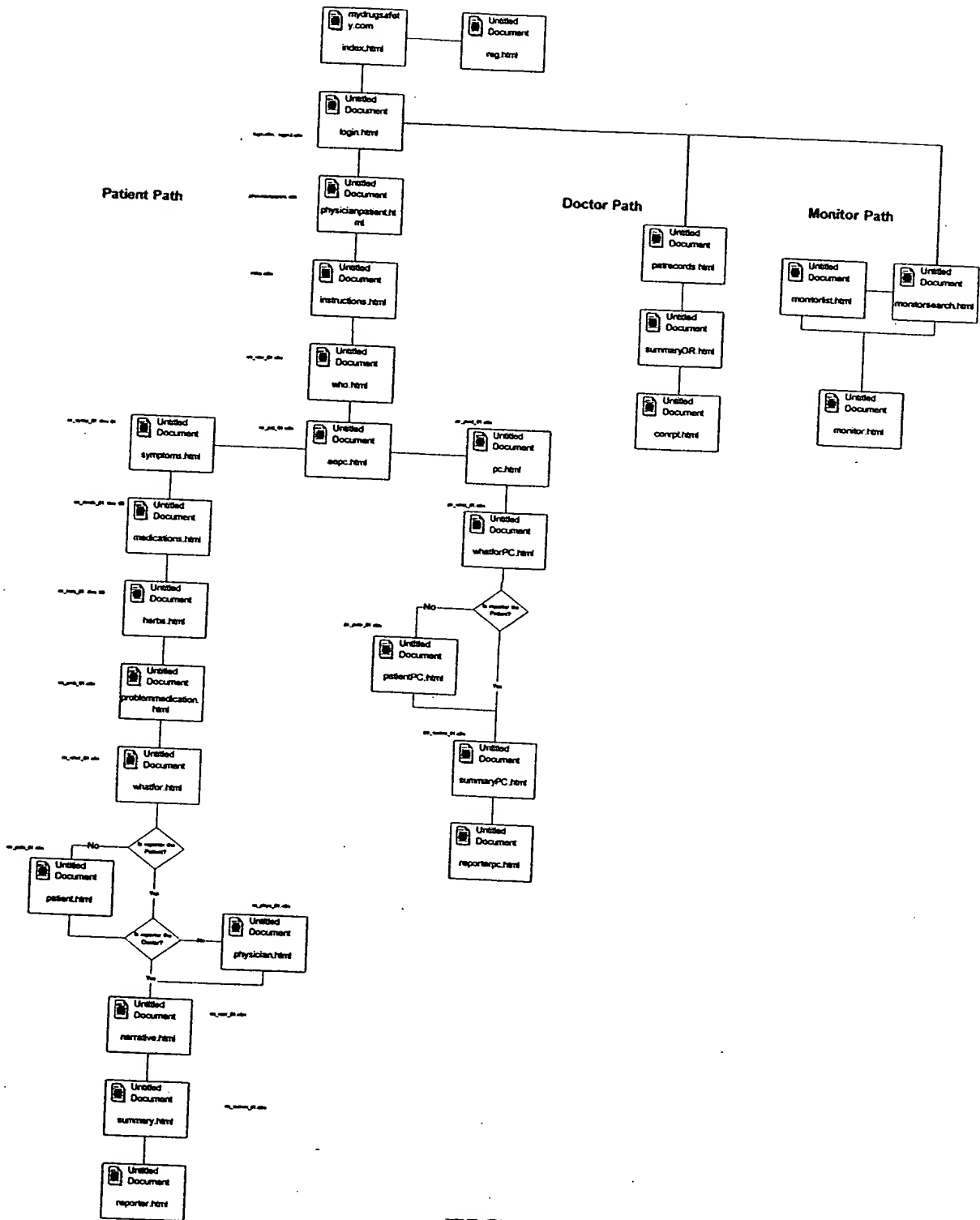


FIG. 3



## Portal Pilot Workflow

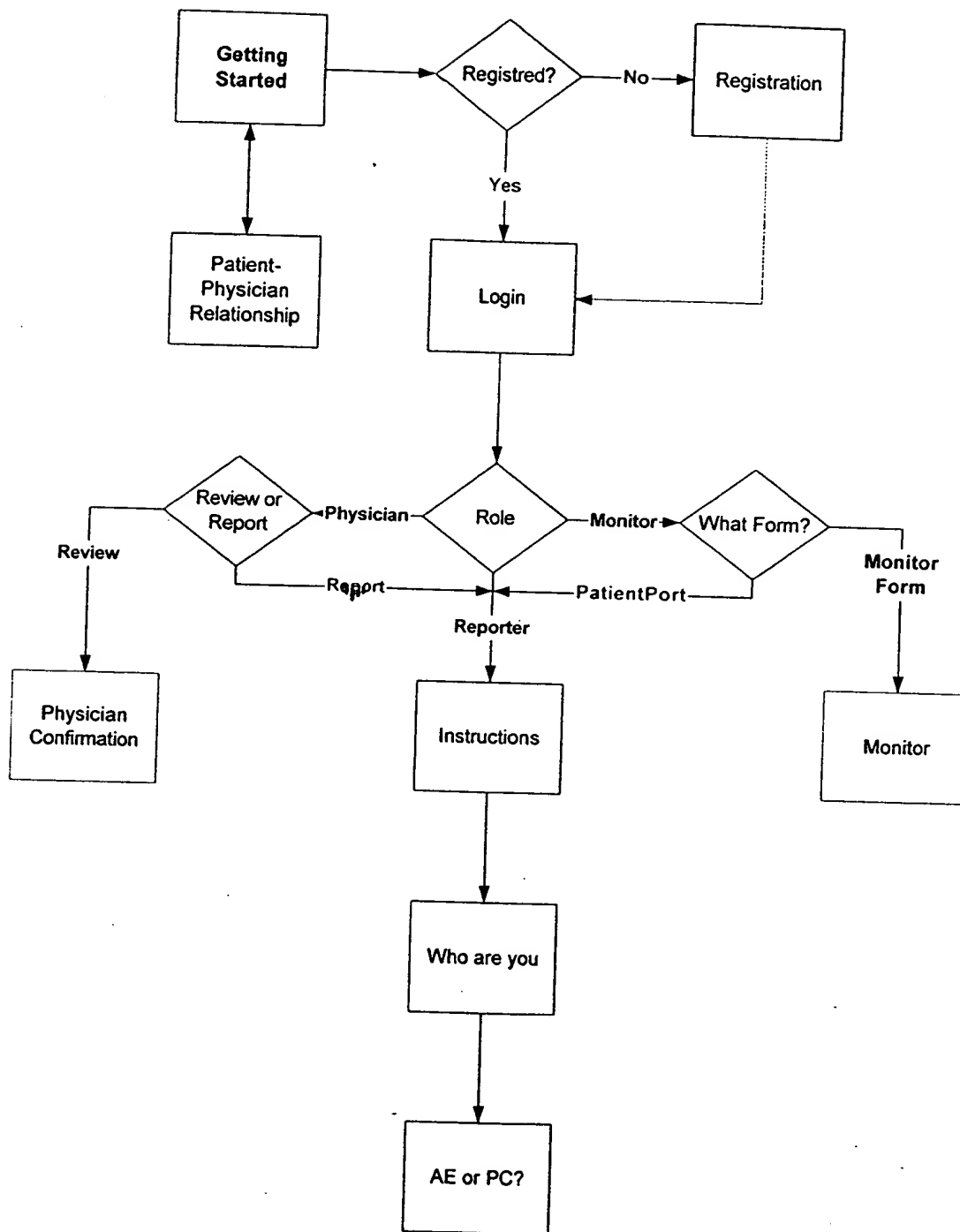


FIG. 3A



## AE or PC Guided Reporting

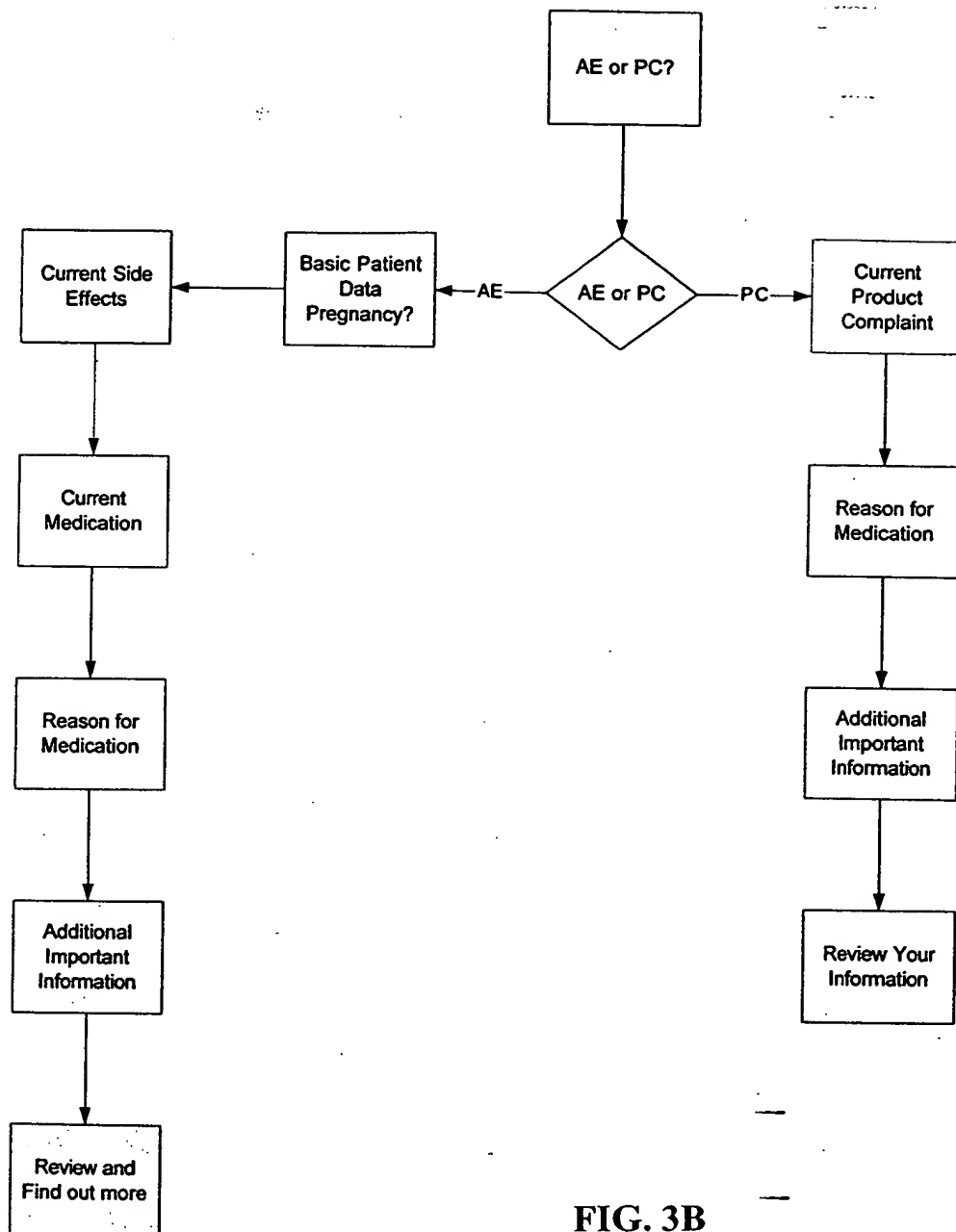


FIG. 3B



## Physician Confirmation

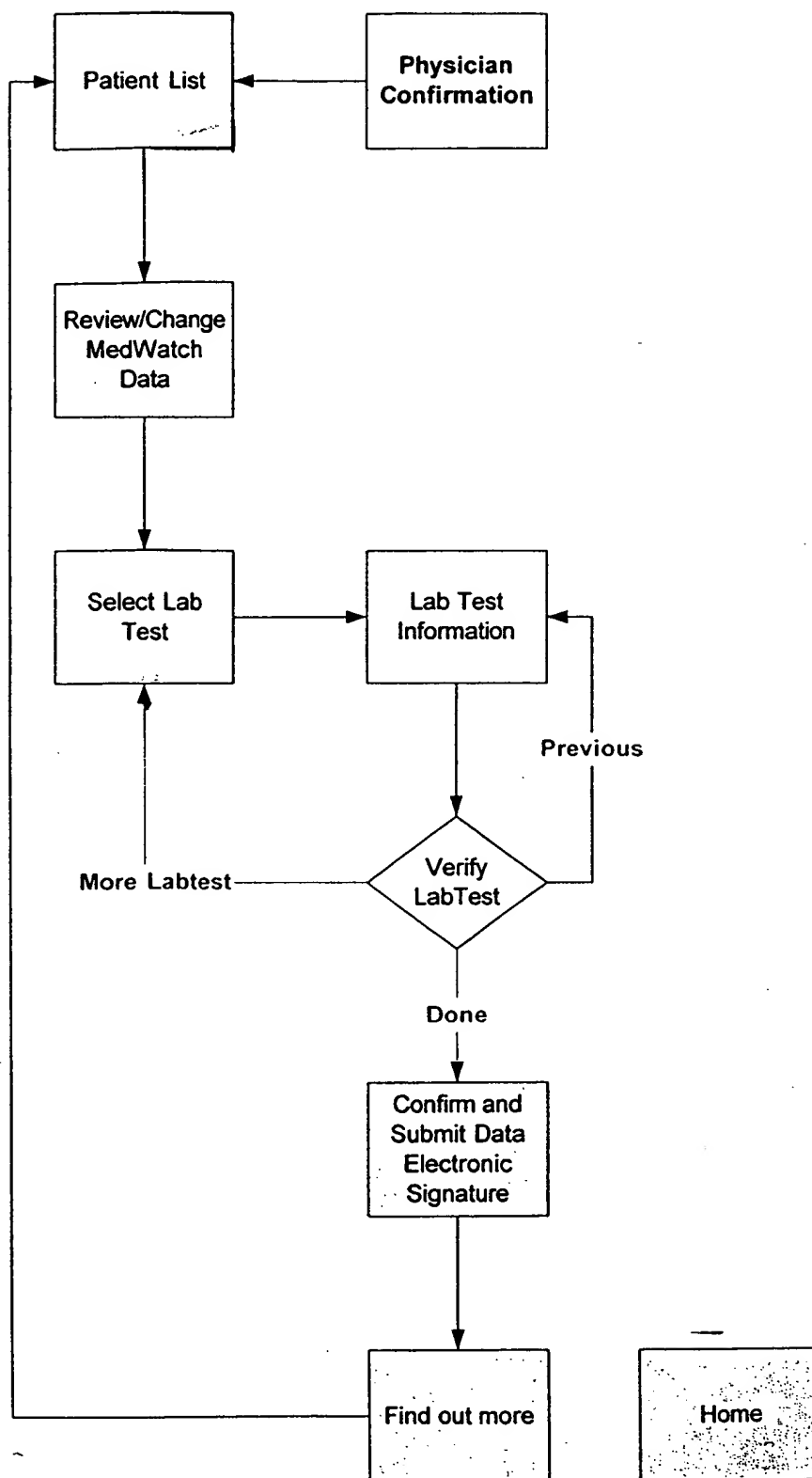


FIG. 3C



## Monitor Form

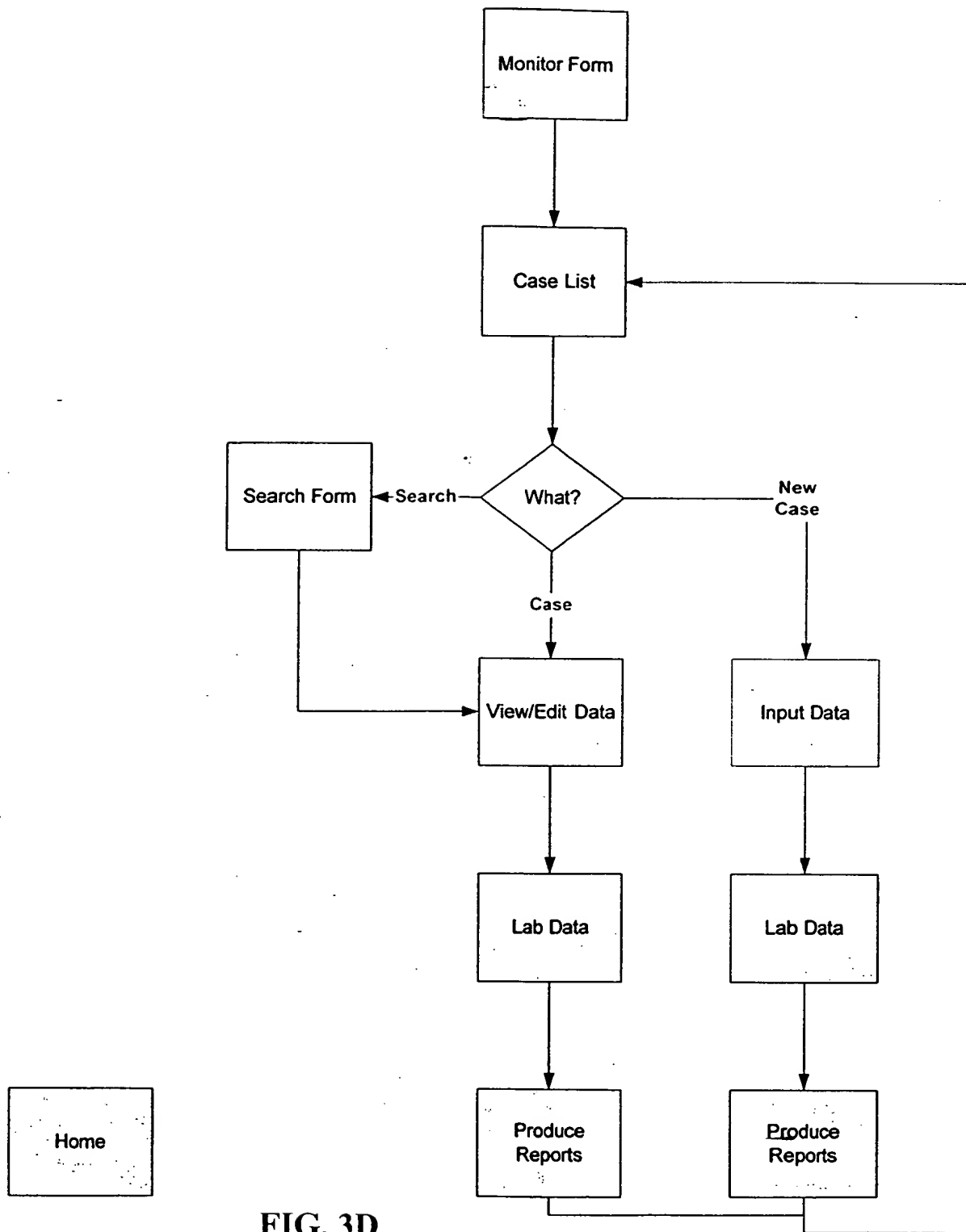


FIG. 3D



## Current Side Effects

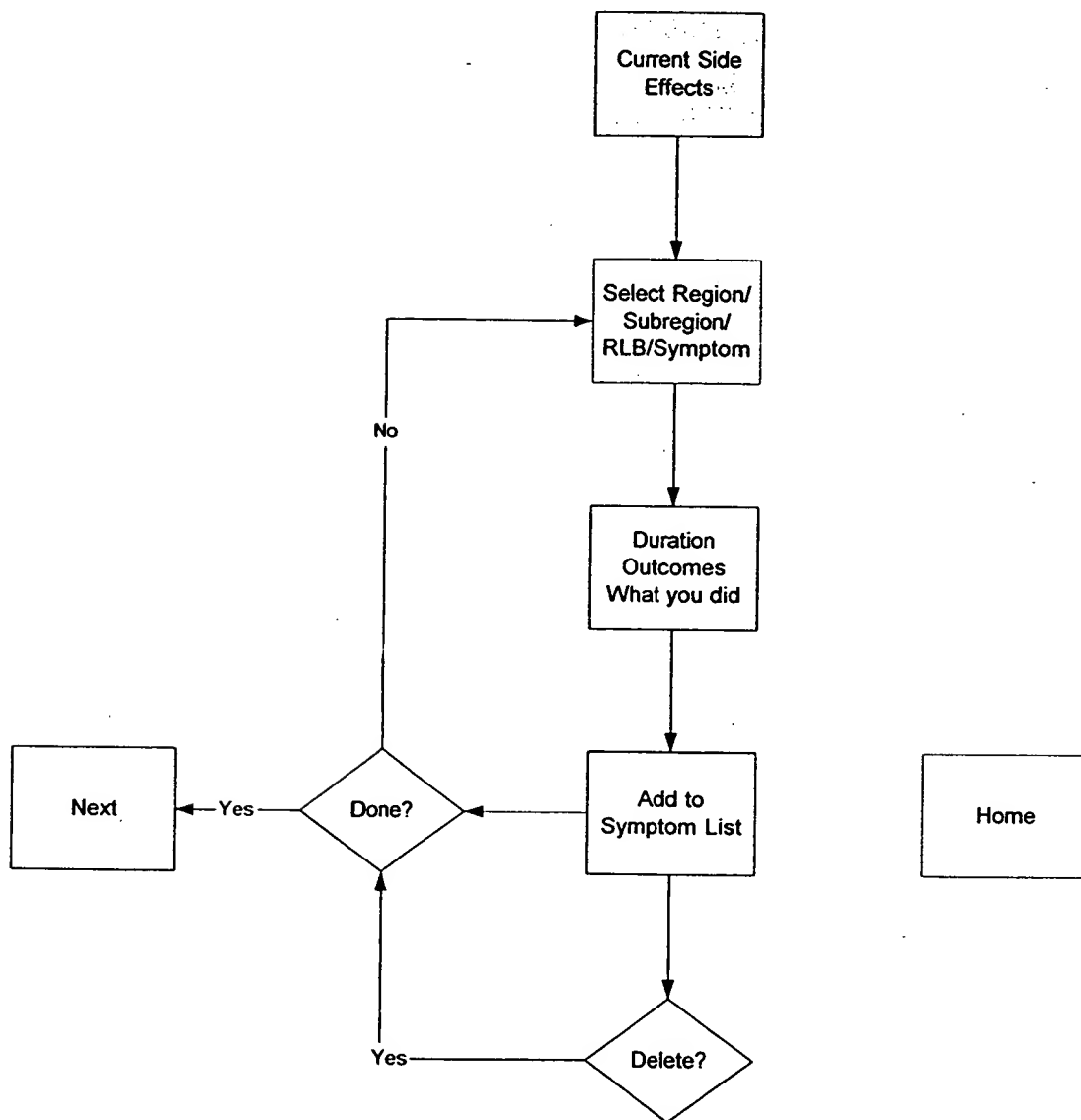


FIG. 3E





## Current Medication

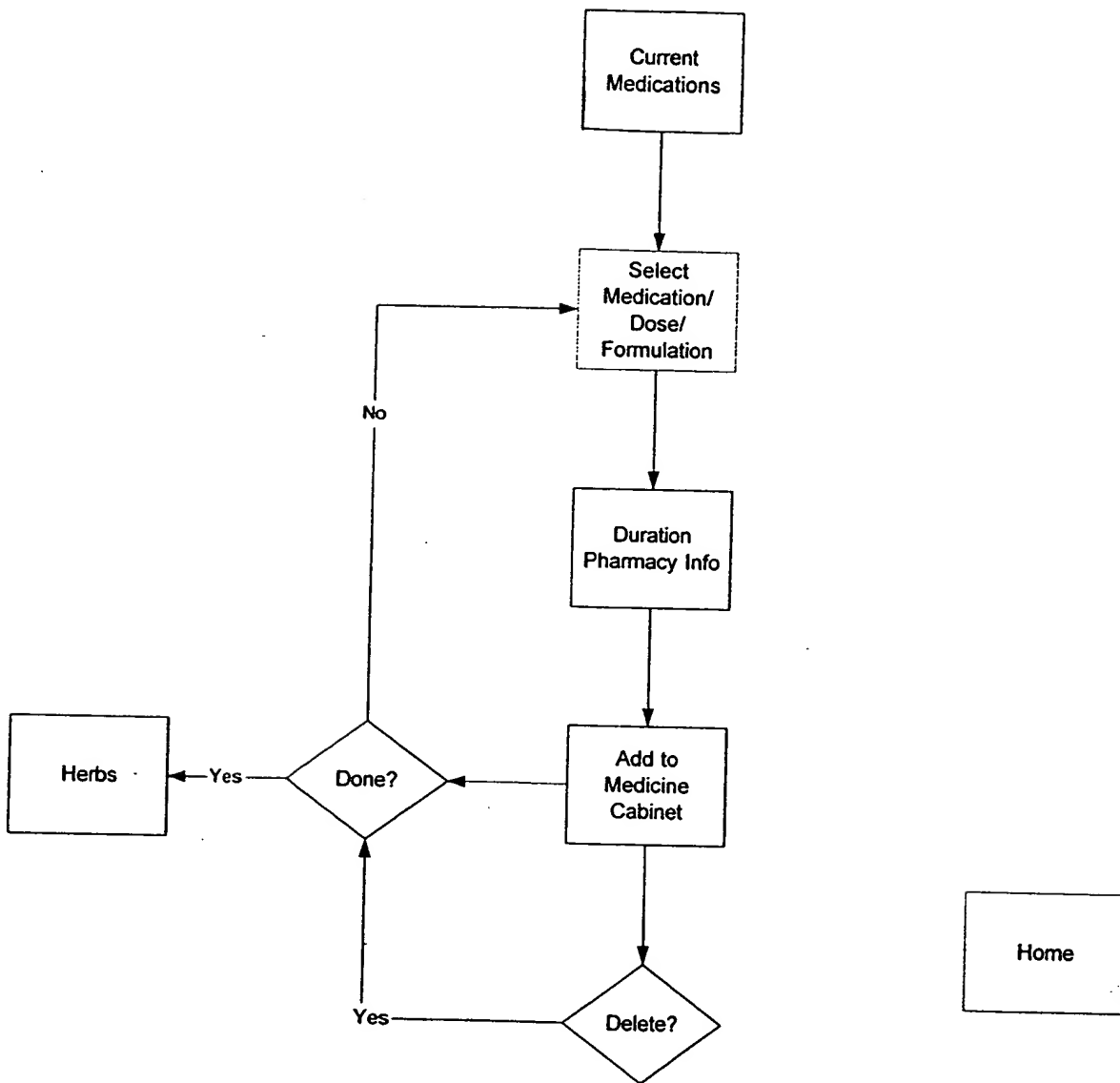


FIG. 3F



Herbs and Nutritional Supplements

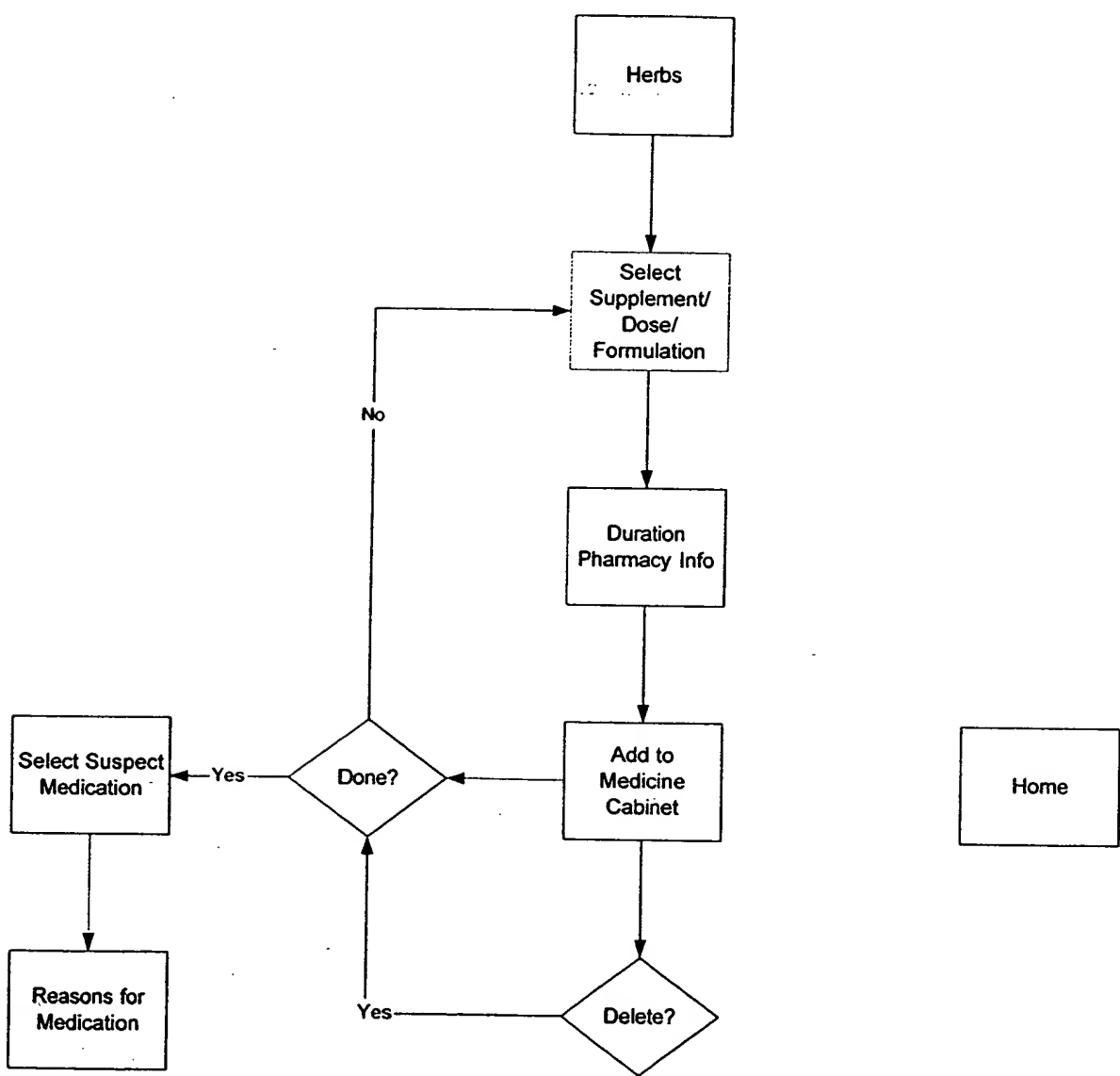


FIG. 3G



## Reasons for Medication

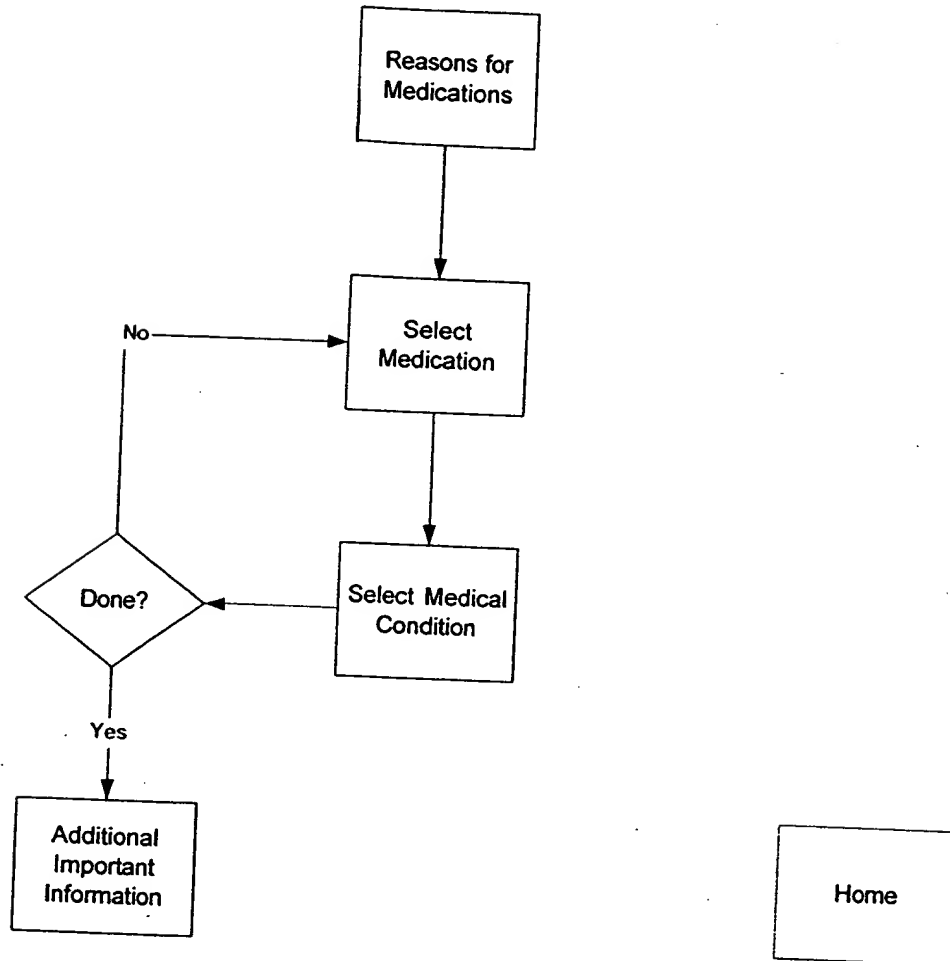


FIG. 3H



## Additional Important Information

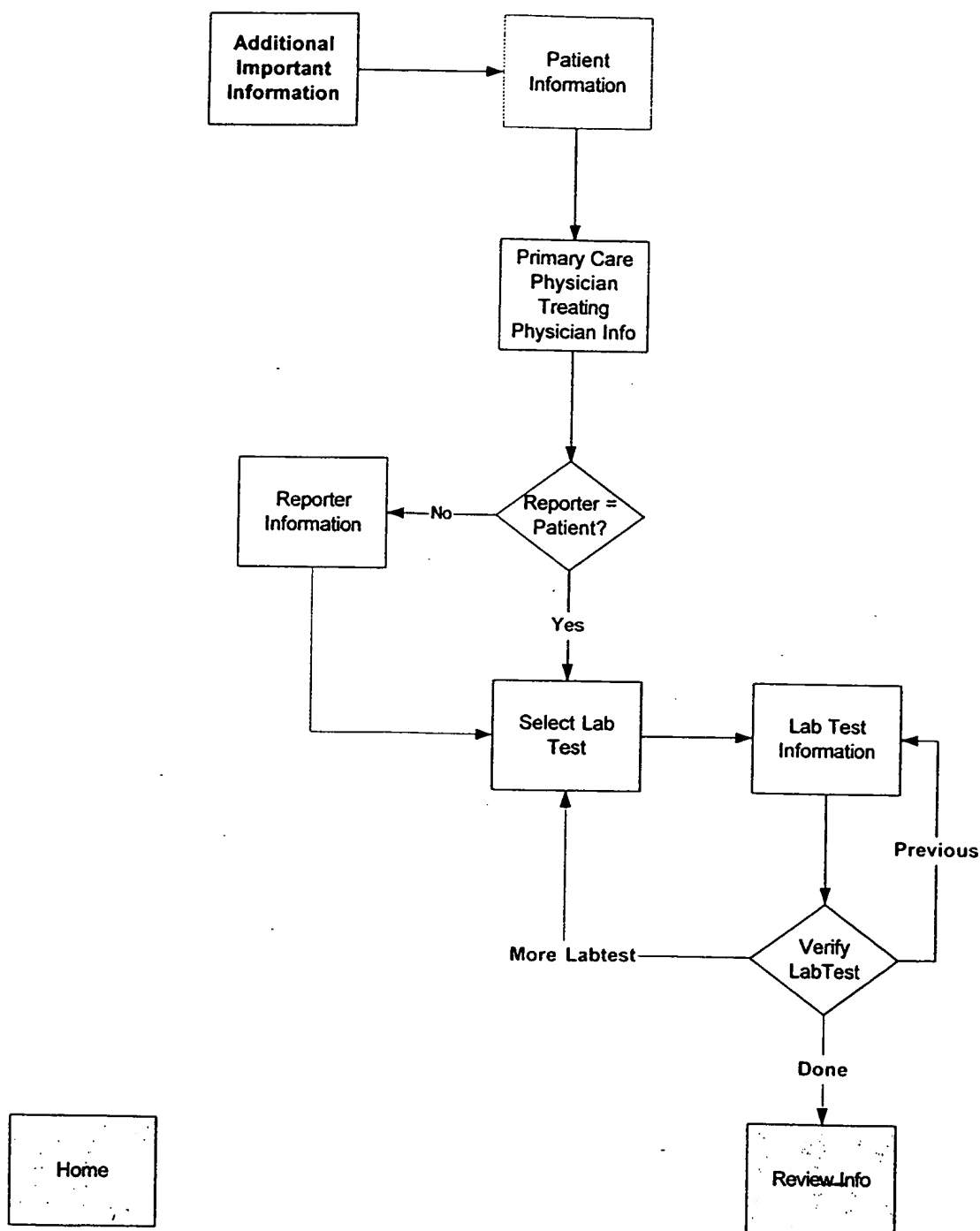


FIG. 3I



## Review Information and Find out More

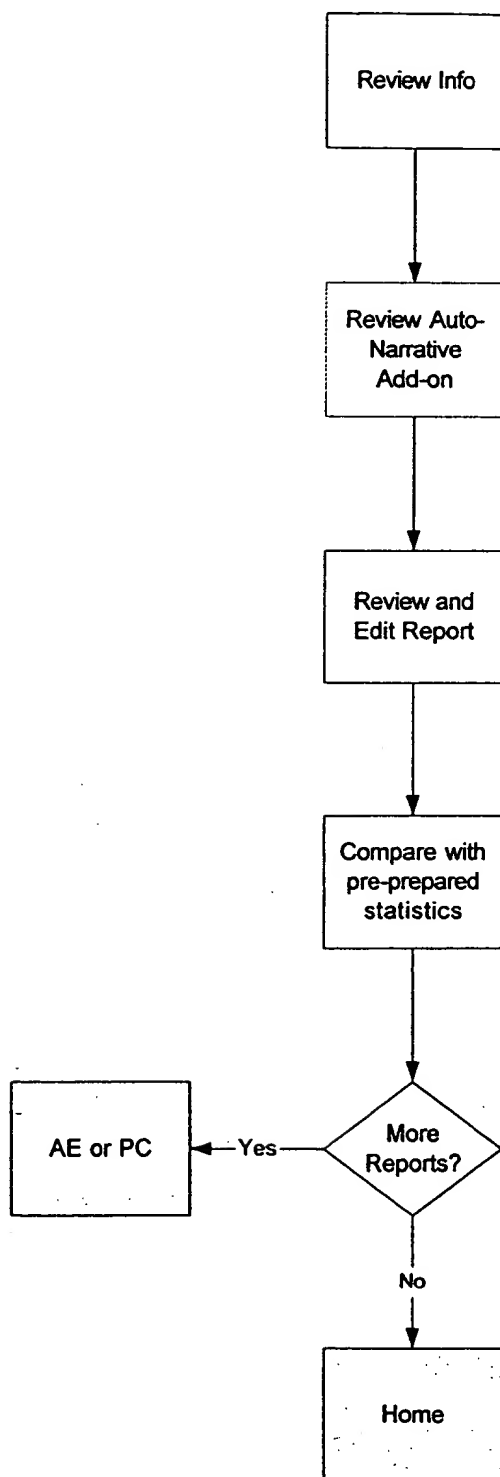


FIG. 3J



### Product Complaint

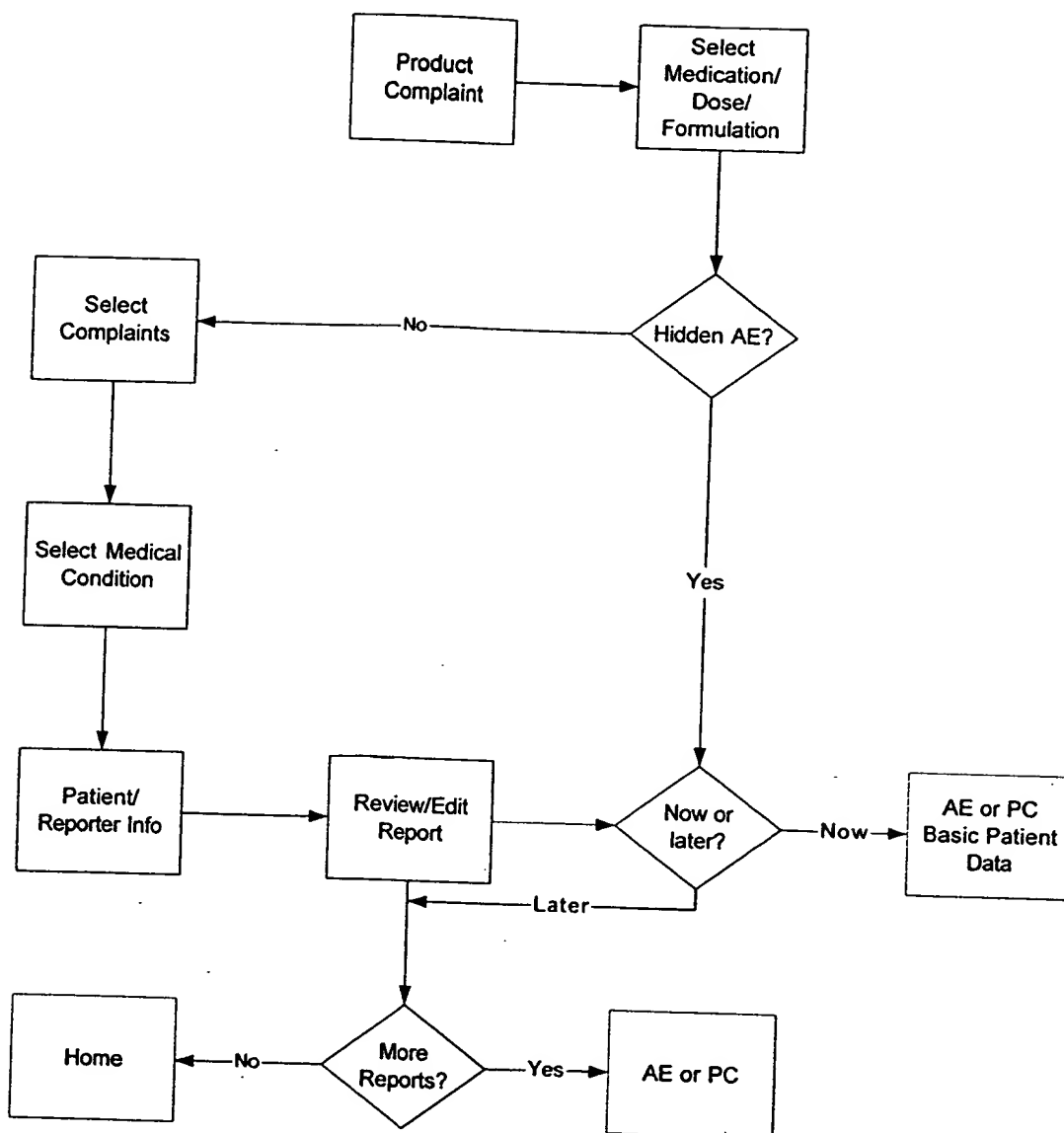


FIG. 3K



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## Registration

### Informed Consent

*In order to complete the report, we may need to contact your physician. Your consent to contact your physician is called informed consent. Only your physician and you will see the information you provide us.*

☐ **Accept** (required to proceed)

This Web Portal is super-secure. To see your information, define a User-ID and password and log in. Forget your password? We can re-create it: 1) define a secret question (ex: What is my favorite football team) 2) define a secret answer (ex: the SF 49ers). Together these will identify you.

### Getting Started

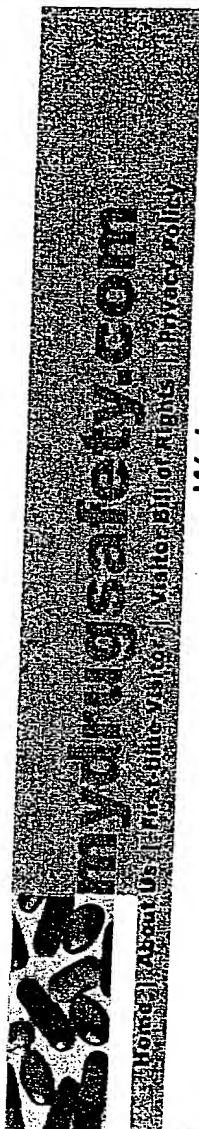
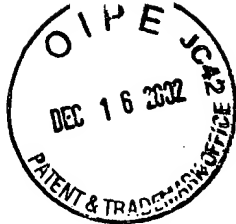
Login/Registration  
Instructions

Who are you  
Side Effects, and/or  
Product Complaints

For this pilot, type the 8 digit registration code printed on your trial card.

First Name	<input type="text"/>
Last Name	<input type="text"/>
User ID	<input type="text"/>
Password	<input type="text"/>
Password again	<input type="text"/>
Secret Question	<input type="text"/>
Secret Answer	<input type="text"/>
Phone Number	<input type="text"/>
E-mail	<input type="text"/>

FIG. 4



Welcome to MyDrug Safety

## Getting Started

First-time user? Go to our registration page.

You will need some information about your medication. As preparation, please get all your medication bottles, packets and containers.

Our reporting process contains 5 easy steps. At the end, you will receive a summary report for review.



The symbol provides online help. If you would like to read all the instructions for all the screens [click here to download](#).

## UserID and Password ?

UserID

Password

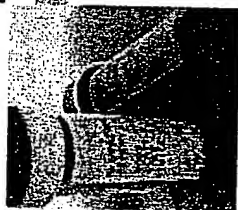
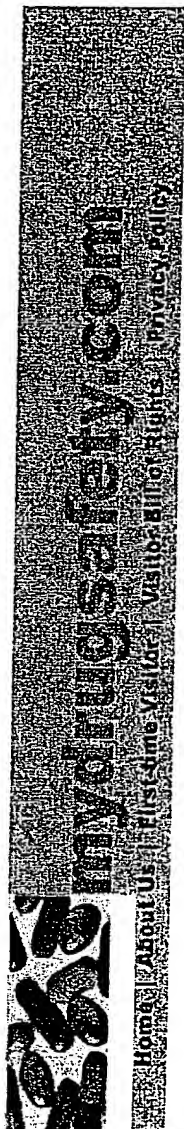
Change your password?

New Password

Repeat Password

FIG. 5





## Patient-Physician Relationship

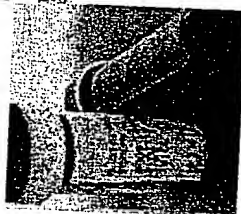
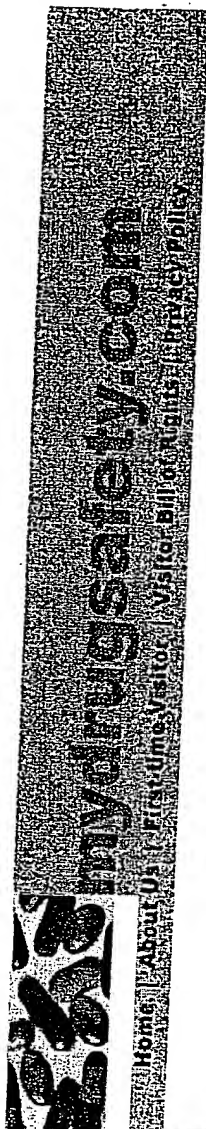
### The Patient/Physician Relationship

To report your information properly, we have to have your physician confirm it. He will not only help you and us to make drugs safer, he can also help you with your side effect. Please provide us with your and your physician's information so that we can call or write back if we need more information. You can do this at any time by clicking on Registration or you will automatically be asked at the end of the process.

There appears to be an incomplete report in progress from the last time you were logged in. Do you want to recover it?



FIG. 6



## Instructions

### Easy steps to report a Side Effect or Adverse Event

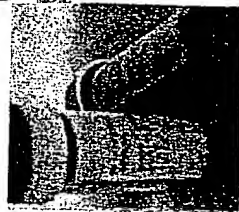
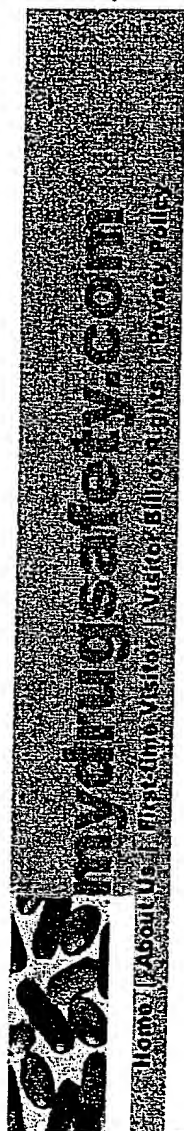
- STEP 1: Side effects or you are experiencing
- STEP 2: Medications you are taking
- STEP 3: Reasons for medication
- STEP 4: Additional Important Information
- STEP 5: Review your report and find out more

### Easy steps to report a Product Complaint

- STEP 1: Product complaint
- STEP 2: Reason for medication
- STEP 3: Additional Important Information
- STEP 4: Review your report



FIG. 7



## Who Are You?



Who Are You?

Family member/spouse

Patient

Patient Caretaker

Pharmaceutical Representative

Someone else? Who?

Treating physician  
---Choose One---

Other Healthcare Professional  
---Choose One---

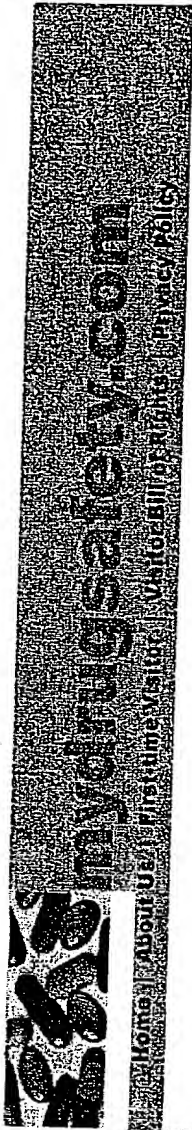


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Help

(helpscreens)

FIG. 8



## Adverse Event or Product Complaint?

### What Do You Want to Report?



Adverse Reaction or a Side Effect you are having

Complaint about your medication

### Family Members Data:

Date of Birth  (mm-dd-yyyy)

or Age

Height   feet  inches  
(ex: 5 feet 2 inches)

Weight  lbs



Pregnant ☒ YES

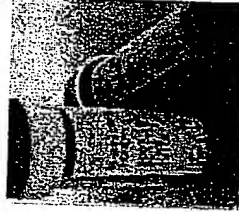
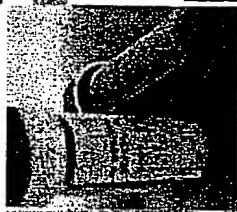


FIG. 9



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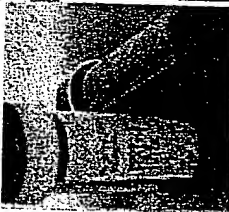

- 1 Getting Started
- 2 Current Side Effects
  - What symptoms are you experiencing?
  - When did the side effects start?
  - What is the severity?
  - What would you like to do?
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

## Adverse Event Define a Symptom

<p>Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.</p>		<p>?</p>	
<p>To delete a symptom from highlight it and press</p> <p>Only when you have finished describing all your symptoms press</p>		<p>Delete</p> <p>Delete</p>	
<p>Click the region where the symptom occurs.:</p>	<p>REGION Which area?:</p> <p>Anus Bladder Buttocks Cervix Groin Labia Minora/Majora Ovaries Rectum Uterus Vagina</p>		
<p>or</p>			

FIG. 10A





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## Adverse Event Define a Symptom

1. Go to the Start

2. Current Side Effects  
What symptoms  
are you having?  
Which body  
part are you  
having it on?

3. Current Medications

4. Reason for Medication

5. Additional Important Information

6. Review Info & Find Out More

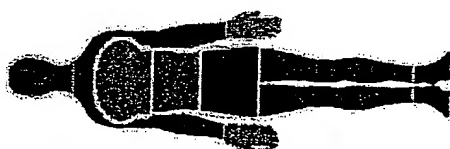
Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

?


Delete

Delete

Click the region where the symptom occurs:



or

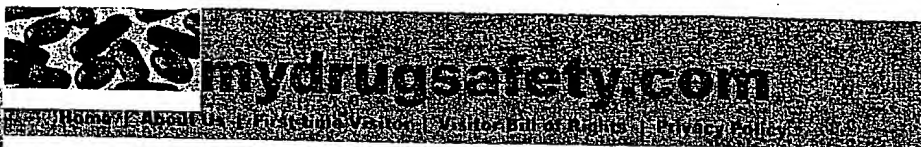


REGION  
Which area?:

Right-Buttocks  
Left-Buttocks  
Both-Buttocks

To delete a symptom from highlight it and press  
Only when you have finished describing all your symptoms press

FIG. 10B




## Adverse Event Define a Symptom

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

Describe your adverse event. Click on a body region and a list of its subparts will appear. Define your symptom by selecting the specific location and the event that occurs. Repeat as necessary. Select a different region by clicking on the figure at left.

To delete a symptom from highlight it and press  
Only when you have finished describing all your symptoms press

Click the region where the symptom occurs:	REGION Which area?:	SYMPTOM What symptom?	DURATION	WHAT YOU DID ABOUT IT
 or General Body	Buttocks	Hip Pain	When did it start? (mm-dd-yyyy) When did it end? (mm-dd-yyyy) OR How Long did it last? Year Is it still there? <input type="checkbox"/> Yes <b>RESULT</b> What was the result of this event? <input type="checkbox"/> Hospitalized under 24 Hours <input type="checkbox"/> Hospitalized over 24 Hours <input type="checkbox"/> Disability <input type="checkbox"/> Congenital Anomaly <input type="checkbox"/> Intervention Needed <input type="checkbox"/> Life-Threatening <input type="checkbox"/> Died (mm-day-yyyy) Other <input type="checkbox"/>	<input type="checkbox"/> Did nothing <input type="checkbox"/> Consulted a Physician <input type="checkbox"/> Stopped Medication <input type="checkbox"/> Reduced dose to <input type="checkbox"/> Switched Medication to <input type="checkbox"/> Did it help? <input type="checkbox"/> Took Medication again and effect came back <input type="checkbox"/> Took something for it. What? Did it help? <input type="checkbox"/> YES Did something else

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Help

(helpscreens)

FIG. 10C



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# What Medication Are You Taking? Medication

1 Getting Started

2 Current Side Effects

3 Current Medications

4 Reasons for Medication

5 Additional Important Information

6 Review Info & Find Out More

Medication:  
Lamisil  
Dose:  
1 %  
Formulation:  
CREAM  
Frequency:  
0 Times a day.

How long

Start

End

Still on it

Optional Info

Lot # of drug? if present

What Pharmacy did you purchase it at?

Name

Zipcode

2

Your Medicine Cabinet

To delete a medication from the list highlight it and press

When your current medication list is complete press

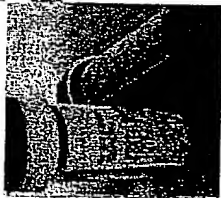
FIG. 11





## What Medication Are You Taking? Suspect Medication

Please select the medication(s) that you think may have caused the event.		?
Your Current Medications Are <input checked="" type="checkbox"/> Lamisil		
<a href="#">PREVIOUS</a>		<a href="#">NEXT</a>



1. Getting Started

2. Current Side Effects

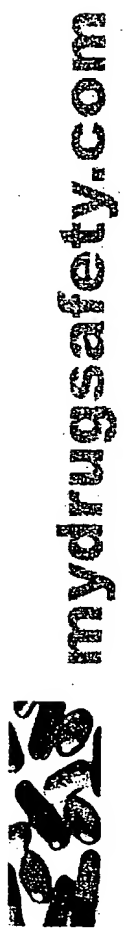
3. Current Medication  
Interactions

4. Reason for Medication

5. Additional Important Information

6. Review and End Our Visit

FIG. 12



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# What Medication Are You Taking?

Herbs or Nutritional Supplements

Tell us what herbs or other supplements you are taking.

Click letter to choose from list.

ABCDEFGHIJKLMNOPQRSTUVWXYZ

Pick one:  select a medication

Not on the list? Enter below

What Dose  select a dose

Times a day

What Formulation?  what formulation

Your Current Herbs

Your Current Medications

&medicine1

&medicine1

How long number of days

Start  mm-dd-yy

End  mm-dd-yy

☐ Still on it

optional info Lot # of supplement? if present

What Pharmacy did you purchase it at?

name  zipcode

?

Add to Medicine Cabinet

Need To delete a medication from your current list? highlight it and press

When your current medication list is complete press

- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications  
Medications  
Herbs & Supplements  
Problem Medication
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

FIG. 13



## Adverse Event What Are You Taking Your Medication For?

What condition are you taking your medication for? Click on your medication and a list of its associated condition/disease will appear. Select the appropriate one. Repeat for each medicine in the list.

Your Medication List			Medical Condition
Medication	Formulation	Dose Frequency (Times a Day)	
Lamisil	CREAM	1 % 4	<div>-----select only one----- Not on the list?...Enter below</div>

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Help

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FIG. 14



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
  - Patient Information
  - Physician Information
  - Lab Test Results
- 6 Review Info & Find Out More

## Adverse Event Lab Results

Tell us what tests were done  
Click letter to choose from list.

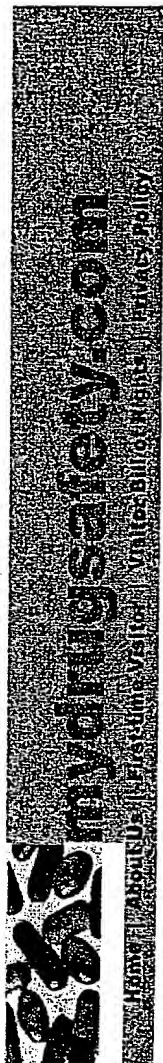
ABCDEFGHIJKLMNOPQRSTUVWXYZ

Then Select the appropriate test and method for the specimen, enter results. Standard Values for the test will be presented with an indicator for whether the patient values are within range or out of range.

Test	Specimen	Method	Min - Max	Test Value Measurement Time & Date	Status of Test
Albumin	Serum	Colimetry	3.5 - 5.0 g/dl	<div>dd/mm/yy</div> <div>g/dl</div> <div>time</div> <div>multiple test values at this date?</div>	
Aldolase				<div>dd/mm/yy</div> <div>g/dl</div> <div>time</div> <div>multiple test values at this date?</div>	
Aldosterone				<div>dd/mm/yy</div> <div>g/dl</div> <div>time</div> <div>multiple test values at this date?</div>	
Alkaline				<div>dd/mm/yy</div> <div>g/dl</div> <div>time</div> <div>multiple test values at this date?</div>	
Phosphatase				<div>dd/mm/yy</div> <div>g/dl</div> <div>time</div> <div>multiple test values at this date?</div>	

FIG. 14A





## Adverse Event Product Complaint

Check your record

This Report

<p>A -30Year old pregnant 1 patient, weighing 110 pounds, height 5 feet 6 inches, was taking Lamisil 1 &amp; CREAM 4 Times a day since 07-01-2000, since [how long] [or continuing], for [indication/condition], reportedly experienced an event ['verbatim or reported' term/symptom (R/L/B)] on [date]. This report was received by [pharmaceutical company or GSS] on [date] from [reporter name].</p> <p>The patient was also taking [prescription medication, over-the-counter or nutraceutical products: concomitant drug 1 (dose, formulation, number of times/day, how long or continuing) for (indication/condition); concomitant drug 2 (dose, formulation, number of times/day, how long</p>
---

Anything to add?

Blablala



- 1 Getting Started
- 2 Current Side Effects
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Find Out More

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Help

FIG. 15



Review Your & Who Record  
Summary Report  
pat1 patlast

Review and edit your report,



- 1 Getting Started
- 2 Current Side Effect
- 3 Current Medications
- 4 Reasons for Medication
- 5 Additional Important Information
- 6 Review Info & Edit Out More

Type over text to edit and only when complete press **Update Report**

A. Patient Information

Patient Name pat1 patlast  
Date of Birth 06-16-70  
Age at Event -30  
Gender ☐ Male ☐ Female  
Pregnant? ☒ Yes ☐ No ☐ Unknown  
Weight 110 Lbs  
Height 5 feet 6 inches  
(ex: 5 feet 2 inches)

B. Adverse Event

Results

☐ Died On (mm-day-yyyy)  
☐ Hospitalized Less than 24 Hrs  
☐ Hospitalized over 24 Hrs  
☒ Disability  
☐ Congenital Anomaly  
☐ Intervention Needed  
☐ Life Threatening  
☐ Other

Date of Event (mm-dd-yyyy)

Date of Report 01-23-2001 (mm-dd-yyyy)

Description

Event Abated? ☐ Yes ☐ No ☐ Unknown  
Event Reappeared? ☐ Yes ☐ No ☐ Unknown

C. Suspect Medications

Drug Name	Dose	Therapy Dates/Duration	Reason
Lamisil	1 %	From 07-01-2000 to 01-01-2001 Duration:1 Year	Disease 2

D. Concomitant Medication

Drug Name	Dose	Therapy Dates/Duration	Reason

Help

(helpscreens)

FIG. 16



# PatientPort<sup>SM</sup>

Home | Wer wir sind | Erstmaliger Benutzer | Datenschutz | Logout

## Arzneimittel-Nebenwirkungen Definieren Sie Das Symptom

**1 Start**  
Login/Registrierung  
Bedienungsanleitung  
Wer sind Sie?  
Arzneimittel-  
Nebenwirkung oder  
Beschwerde über das  
Arzneimittel

**2 Arzneimittel-Nebenwirkung**  
Ihre Symptome  
Beginn und Ende  
Direkte Auswirkungen  
Gegenreaktionen

**3 Ihre Medikamente**  
Medikamente  
Andere Medikamente  
Heilkräuter & Vitamine

**4 Weshalb nehmen Sie?**

**5 Zusätzliche Informationen**  
Patienten-Report  
Nebenwirkungen

**6 Bestätigen Sie Ihre Daten**  
Ihre generierten Berichte  
Alle Ihre Daten  
Vergleich mit anderen  
Berichten der FDA

Wir bitten Sie, im folgenden Ihre Arzneimittel-Nebenwirkungen zu beschreiben. Klicken Sie bitte eine Körperebene an und es wird eine Liste von Sub-Regionen erscheinen. Definieren Sie Ihr Symptom, indem Sie zuerst den genauen Ort bestimmen und dann ein Symptom aus der präsentierten Liste auswählen. Durch Anklicken der Figur können sie nachher weitere Regionen auswählen.

Ihre Symptome  
Augen, verschwommene Sicht  
Augen, verengte Pupillen

Um ein Symptom zu löschen, markieren Sie es bitte und drücken Sie  
Erst wenn Sie alle Ihre Symptome abschliessend beschrieben haben, drücken Sie bitte



Klicken Sie bitte die Region, in der Ihr Symptom sich äussert	KOPF Wählen Sie die Region?	SYMPTOM Ihr Symptom	DAUER	WAS UNTERNEHMEN SIE DAGEGEN?
	AUGEN	VERENGTE PUPILLEN	Beginn des Symptoms mm-dd-yy Ende des Symptoms mm-dd-yy Wie lange dauerte es? Tage <input type="text"/> Besteht das Symptom immer noch? <input type="checkbox"/> JA	<input type="checkbox"/> Nichts <input type="checkbox"/> Konsultierte einen Arzt <input type="checkbox"/> Stoppte die Medikamenten-Einnahme Reduzierte die Medikamenten-Dosis auf <input type="text"/> <input type="checkbox"/> Wechselte das Medikament auf <input type="text"/>
			AUSWIRKUNG DES SYMPTOMS Hatte das Symptom direkte medizinische Auswirkungen, wie Hospitalisierung unter 24 Std <input type="checkbox"/>	Half es? <input type="checkbox"/> JA <input type="checkbox"/> Nahm das Medikament wieder und der Effekt erschien wieder <input type="checkbox"/> Nahm ein Gegenmittel. Was? <input type="text"/>
			SYMPTOM ZUR LISTE HINZUFÜGEN	

FIG. 16A

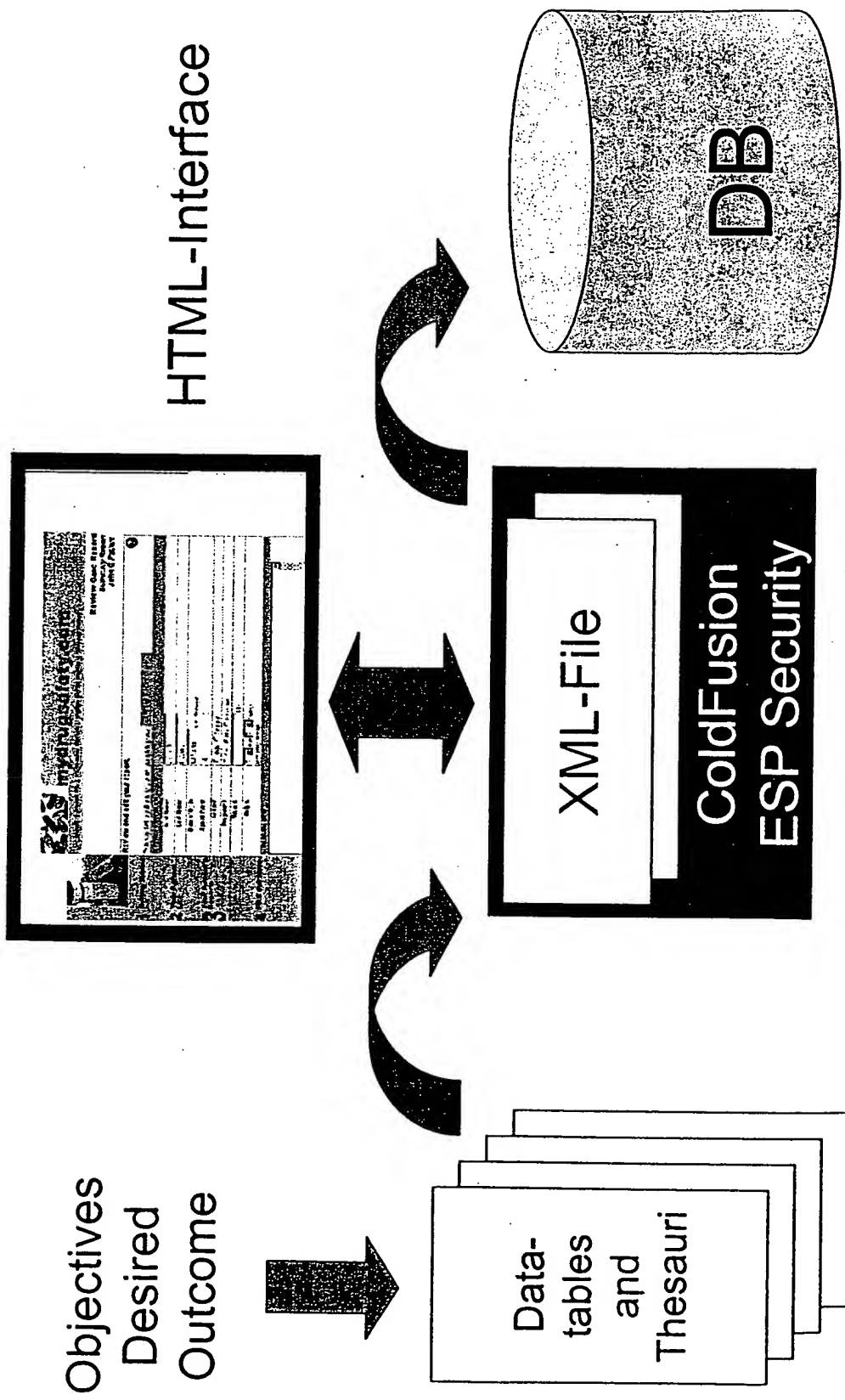


FIG. 17



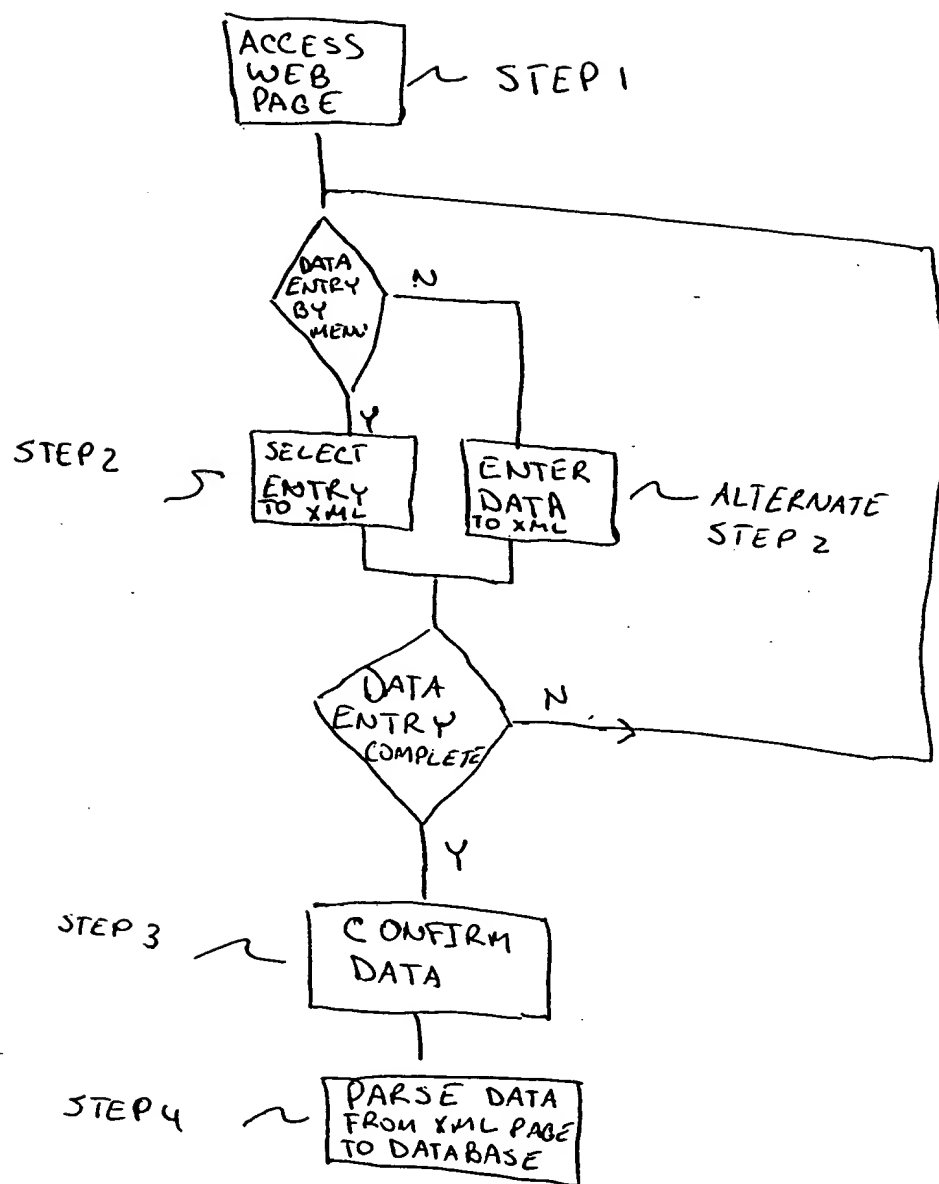


FIG. 18